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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/601,005	03/01/1996	KJELL BACKSTROM	06275/034001	2853

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EXAMINER

CHOI, FRANK I

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 01/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

### Office Action Summary

**Application No.**

08/601,005

**Applicant(s)**

BACKSTROM ET AL.

**Examiner**

Frank I Choi

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 46,54-77 and 80-107 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 46,54-77 and 80-107 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

This is a supplemental Office Action, in response, to a Preliminary Amendment which was received by the Office on December 17, 2003, prior the mailing date of Office Action (12/18/2003).

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 46, 54-77,80-107 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Evidence that the claims fail to correspond in scope with that which applicant(s) regard as the invention can be found in Paper No. 34 filed (9/23/2003). In that paper, applicant has stated the formulations are non-aqueous, and this statement indicates that the invention is different from what is defined in the claim(s) because the claims do not exclude the presence of water. The preliminary amendment does not appear to specifically address this issue.

Claims 76, 77, 80-95, 106,107 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: that medicament is for inhalation. The Specification appears to indicate that the medicaments are required to be "a medicament for inhalation" as defined on pg. 5 of the Specification, as such, the claims should recite the same. The amendment "inhaled medication" is not sufficient. The Specification explicitly sets forth the type of medication and a defined term, i.e. "medicament for inhalation".

*Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 46,54-77, 80-107 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 91/11495 in view of Neale et al. (US Pat. 5,688,782), Sequeira et al. (US Pat. 5,837,699) and Meezan et al. (US Pat. 5,661,130) for the reasons of record set forth in the prior Office Actions and the further reasons below.

WO 91/11495 teach a medical aerosol containing 1,1-difluoroethane, 1,1,1,2-tetrafluoroethane and/or heptafluoropropane and surfactant(s), where the medicine includes betamimetics, such as salmeterol, and steroids, such as budesonide (Pgs. 2-5).

Neale et al. teach that medical aerosols containing fluorocarbons, adjuvants such as ethanol, and surfactants wherein the medicine includes beclomethasone, fluticasone, budesonide, salmeterol, formoterol (Columns 3, 4).

Sequeira et al. teach a medical aerosol containing mometasone, fluorocarbons, such as HFC-134A or HFC-227, and surfactants (Column 5).

Meezan et al. teach that alkyl saccharides are ideal penetration enhancers, i.e. surfactants, for medical aerosols, including for administration of proteins and peptides, in that they are effective but are non-toxic as opposed to other known penetration enhancers (See entire document, especially columns 2,3,5).

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The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the combination of fluorocarbons, medicine and alkyl saccharides in a pharmaceutical aerosol formulation. However, the prior art amply suggests the same as it is known to produce pharmaceutical aerosols containing fluorocarbons and surfactants and that alkyl saccharides are suitable for use as surfactants in medical aerosols. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the medical aerosol would exhibit increased bioavailability of the administered medicine(s) and would be suitable for administration of a broader range of medicines.

Examiner has duly considered Applicant's arguments but deems them unpersuasive for the reasons set forth in the prior Office Actions, including the Advisory Action (10/02/2003) and the further reasons below.

Applicant argues that the disclosure in Neale et al. is limited to the unique situation posed by beclomethasone and is not reasonably extendable beyond that special case. However, Neale et al. specifically discloses the suitability of the product for delivery of a variety of other inhaled medicaments (Neale et al., Column 4, lines 29-68, Column 5, lines 1-5). Applicant argues that Meezan et al. suggests the use of surfactants with a HLB of 10 to 20, preferably 11 to 15. Meezan et al. actually states that "a preferred surfactant has an HLB of from 10 to 20 and an even more preferred range of from 11 to 15." (Meezan et al., Column 5, lines 4-17). Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as

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somewhat inferior to some other product for the same use.” In re Gurley, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). Applicant argues that nothing in Meezan et al. suggests that alkyl saccharides could be used in non-aqueous organic media, however, as admitted by Applicant and disclosed in Meezan et al. (See Meezan et al., Column 4, lines 53-59) surfactants can be formulated to have greater hydrophobicity, and, thus, lower HLB's. Applicant argues that the fact that alkyl saccharides are safe and non-toxic is irrelevant. However, it is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant, i.e. the same motivation. In re Linter, 173 USPQ 560 (CCPA 1972); In re Dillon, 16 USPQ2d 1897 (Fed. Cir. 1990), cert. denied, 500 U.S. 904 (1991). Applicant argues that one of ordinary skill in the art familiar with the properties and activities of surfactants between aqueous solutions and non-aqueous, organic hydrocarbon propellant would have not expected the behavior of alkyl saccharide dissolved in aqueous solution would be at all similar to its behavior when suspended as dry particles in a non-aqueous, organic media. However, the mere fact that Meezan in its preferred examples discloses the use of an alkyl saccharide in aqueous solutions does not make the claimed invention unobvious. As indicated above, it is well within the skill of one of ordinary skill in the art to adjust the HLB of the alkyl saccharide surfactant as desired, and, thus, be used in formulations requiring lower HLB's.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

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***Conclusion***

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Thurman Page, can be reached on (703) 308-2927. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (703) 308-1235 and (703) 308-0198, respectively.

FIC

January 20, 2004



JOHN PAK  
PRIMARY EXAMINER  
GROUP 1600